

OCT 16 2008

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Glenn G. Strawder

Serial No.: 09/865,696

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For: A Method For Monitoring Radiology Machines, Operators and Examinations

DECLARATION OF GLENN G. STRAWDER

Honorable Commissioner of Patents

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Sir:

I am the applicant.

I have worked in the medical field of Radiology for over 38 years. I have worked in large to small hospitals, medical clinics and private physicians offices in many states across this country. Working for these various facilities was an enormous educational benefit.

I have worked at Highland General Hospital, Merritt Hospital, Peralta Hospital and San Francisco General Hospital in California, Deaconess Medical Center and the University of Washington Medical Center in Washington, Flagstaff Medical Center and Phoenix Baptist Hospital in Arizona, University of Colorado Hospital in Denver Colorado, Meharry Medical Center and Nashville Baptist Hospital in Tennessee, Bethany Methodist and Cook County Medical Center in Chicago, Savannah Memorial University Medical Center in Georgia, Holy Cross Hospital and Montgomery Hospital in Maryland, the Washington Hospital Center and Georgetown University Hospital in Washington D.C. and J. T. Mather Memorial Hospital on Long Island, New York.

In my career, I have worked as a staff technologist, a senior technologist, a special procedure technologist, CT Technologist and several levels of management such as assistant chief of the radiology department.

In my experiences, all across this country (as in most jobs) some x-ray technologists can perform their duties above the standard level, some at the standard level and some below the standard level.

In the field of Radiologic Technology, sooner or later every x-ray technologist one makes a mistake and must retake one or more of the pictures in an examination. Since radiation is the primary source used in radiology, retaking a picture whether it is due to the technologist error or the patient for many times a patient will breathe or move during the taking of a picture and thereby obscure the imaging. The additional exposure of radiation is harmful to the patient. Also, since each picture requires the use of more materials (supplies) and time added to the exam, the cost to retake a picture adds to the high cost of healthcare. The average cost to retake one x-ray picture is over \$7.50. That's \$1 for the film, \$1 for the wear and tear of the equipment used, \$1.50 to process (develop) the film, 15 additional minutes or \$4 to \$7 added to the examination of the staff technologist time (average staff technologist salary in the Washington D.C. Metropolitan area is over \$20/hr) not to mention the additional time of the Radiologist to read the retake picture.

When I serviced as the assistant chief of the Radiology Department at J. T. Mather Memorial Hospital in Port Jefferson, Long Island, N.Y., I had a day staff of about 6 technologists back in the 70's (this number as almost double now) and could not watch any of them perform any entire examinations. On average, during an eight hour period (the day shift) 60 to 80 x-ray examinations were performed .

This does not include portable x-rays or examinations in other modalities such as special procedures, CT Scan, etc. The average x-ray examination requires 3 pictures or views (AP, oblique and lateral). Out of 180 to 240 x-ray pictures per day shift, approximately 15% or 27 to 36 pictures had to be retaken. That's a substantial amount of money added to the daily cost to do business and a substantial amount of extra radiation given to patients. The above percentage of error also applied to the other eight hour two shifts per day, the weekend 24 hour coverage of the hospital and the other modalities of Radiology.

If I did not know (which was the case most of the time since I had many duties) that a technologist made an error, the error without correction would often be repeated daily over and over again (since most workers do not tell management that they are making the same error over and over again).

No one has solved this very cost and potential dangerous problem today. There is no present way of checking the proficiency of operators of medical imaging machines other than to have the supervisor stand directly behind the operator when running the machine, which is too costly, and time consuming.

With my invention the various steps of an operator will be checked against a standard set of steps and any errors are determined by the computer.

When a supervisor of a medical imaging department reviews my invention's output he or she will find not just the error that one of their staff technologist has made but the actual step or steps that were not properly done during the examination where the error was made and he or she can direct a rerun to thereby make sure that the patient gets a correct result. Also, my invention allows the supervisor to monitor the x-ray technologist during each examination without being present and see where in the examination they are having problems

with those desired.

Prince Col. 12, lines 9-36 says and I quote, "A mechanical injector is preferred because of the greater reliability and consistency when compared to injecting by hand. Since the magnetic field interferes with normal functioning of electronic devices, a pneumatic powered, spring loaded or other non-electric pump may be suitable. It should be noted, however, that as electrical pump may be used if its operation is unaffected by the operation of the magnetic resonance imaging system, e.g., if the pump is adequately shielded or if it is located sufficiently far from the magnet. In one preferred embodiment, the mechanical infusion device 12 is coupled to the magnetic resonance imaging system 16 to facilitate proper or desired timing between the injection of the magnetic resonance contrast agent and the acquisition of the image data, in addition to providing proper or desired rate of infusion of the contrast agent.

In another preferred embodiment, proper or desired timing and rate of infusion of the contrast agent are controlled through a control mechanism as the mechanical infusion device 12. That is, the mechanism that controls the infusion timing and rate of infusion is implemented within the mechanical infusion device 12. In this circumstance, the mechanism infusion device 12, is a "self-contained" unit.

As mentioned above, the infusion device 12 injects the magnetic resonance contrast in a strictly controlled manner." Nowhere does Prince suggest, teach or show motivation of a computer for storing a first series of steps that an operator should perform when using said medical imaging machine and storing a second series of steps that set forth what the operator of said medical imaging machine actually performed during the use of said machine and comparing said first series

of steps with said second series of steps.

Even if the combination of Howson, Prince and Dorne is made it does not meet the claims of the applicant, none of Howson, Prince and Dorne do not teach:

“an apparatus for monitoring the operations of an operator of a medical imaging machine used to perform a medical function, comprising:
a computer for storing a first series of steps that an operator should perform when using said medical imaging machine to perform said medical function,
said computer also storing a second series of steps that set forth what the operator performed during the use of said medical imaging machine to perform said medical function,
said computer comparing said first series of steps with said second series of steps.”

MPEP Sec. 2143.03 says quote:

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Royke*, 490 F.2d 981, 180 USPQ (CCA 1974).”

MPEP Sec. 2143.01 says quote:

“Obviousness can* be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006).”

Claim 65 patentably defines over the prior art by calling for,

“...a computer for storing a first series of steps that an operator should perform when using said medical imaging machine to perform said medical function,
said computer also storing a second series of steps that set forth what the operator performed during the use of said medical imaging machine to perform said medical function,
said computer comparing said first series of steps with said second series of steps.”

which is not in Howson, Prince or Dorne.

Claim 66 is patentable as it calls for, “prices computed from the operations performed by the operator of said medical imaging machine.”

Claim 67 is patentable as it calls for, “a plurality of medical imaging machines each of which performed a medical function and produces a picture of a body part in which said computer comparing at least first series of steps of each said medical imaging machines with a second series of steps for each of said medical imaging machines.”

Claim 68 is patentable since it calls for, “plural medical imaging machines and plural computers, including at least one computer for each medical imaging machine so that each operator of a medical imaging machine can be monitored at the same time.”

Claim 69 is patentable as it call for,

“...storing in said computer a predetermined series of steps for operating said medical imaging machine to perform a medical function,
entering into said computer the actual series of steps of said operator in operating said medical imaging machine, and
comparing said predetermined series of steps with said actual series of steps of said operator.”

which is not in Howson, Prince or Dorne.

Claim 70 is patentable as it calls for, "computer computes prices useful, for billing purposes, from the operations of said medical imaging machine."

Claim 71 patentably defines over the prior art by calling for,

"a plurality of medical imaging machines each of which performs a medical function and also produces a picture of a body part of a patient, providing a separate operator for each of said medical imaging machines, with each operator performing a series of steps while operating a machine, and comparing said predetermined series of steps with the actual series of steps of each operator."

Claim 72 is patentable as it calls for, "computer provides information on procedures performed on each of said medical imaging machine as well as summaries of the operations of all of said medical imaging machine."

Claim 74 is patentable as it calls for, "said medical imaging machine to be an x-ray machine."

Claim 75 is patentable as it calls for, "said medical imaging machine to be a radiology imaging machine."

Claim 76 patentably defines over the prior art by calling for,

"providing a medical imaging machine which requires an operator to make a series of steps in order for said medical imaging machine to produce a picture of a body part of a patient, providing a computer, storing in said computer data which represents predetermined steps of said operator during the use of said medical imaging machine to produce a picture of a body part of a patient, entering into said computer actual steps that said operator performed in operating said medical imaging machine to produce a picture of a body part of a patient, and said computer comparing said actual steps with said predetermined steps."

which is not in Howson, Prince or Dorne.

Claim 77 patentably defines over the prior art by calling for,

“a computer,
said computer including means for storing at least two predetermined steps that an operator should perform when using said medical imaging machine used to take a picture of a body part of a patient, said computer receiving and storing at least two of the actual steps that the operator performed during the use of said medical imaging machine used to take a picture of a body part of a patient, and said computer comparing said at least two predetermined steps with said at least two actual steps entered into said computer.”

which is not in Howson, Prince or Dorne.

Claim 78 is patentable as it calls for, “said medical imaging machine is an x-ray machine.”

Claim 79 is patentable as it calls for, “said medical imaging machine is a radiology imaging machine.”

Claim 80 is patentable as it calls for, “said medical imaging machine is a CT scanner machine.”

(2) The claims produce new and unexpected results

Applicant Strawder has worked in the medical field of Radiology for over 38 years. Today, Congress, the American Medical Association, Insurance Providers like Medicare as well as patients want accountability in healthcare. They want and need accurate and objective ways to monitor and measure the proficiency of performance.

Insurance providers such as Medicare are adopting new ways such as pay for performance to ensure that their patients are receiving standard care for the money being paid. Insurance providers want measures in place that will help monitor operator performances. Healthcare providers want and need measures that will help them monitor their operators performances and help them understand where they may fall short.

In Radiology, not all but most medical imaging machines deliver a dose of radiation to produce each picture or deliver a treatment. There is a fee or cost associated with each picture. In addition, radiation is accumulative and any amount is considered harmful. Therefore, taking over or repeating a picture due to operator error is not only costly to the patient but also costly to the medical facility. Increasing the proficiency of operators of medical imaging machines makes it safer for the patient and less costly for all (the medical facility, insurance company and the tax payers).

With the advancements of Digital Radiography and CT Scan has come many benefits and more radiation. This trade off of greater image resolution and increase in radiation will always exist and advancements in these fields will not and can not stop.

Operators of medical imaging machines perform substandard work on patients when medical facilities prefer quantity of work to quality of work. As a results many patients are over radiated as well as get an inferior result even though they pay full price.

There is no present way of checking the proficiency of operators of a medical imaging machine other than to have the supervisor stand directly behind the operator when running the machine, which is too costly, time consuming and will never happen. In that scenario, there would have to be one supervisor for each operator and it would be cheaper to just have the supervisor perform the test.

With Strawder's invention the various steps of an operator will be checked against a standard set of steps and any errors are determined by the computer.

If the supervisor of a medical imaging department when reviewing Strawder's invention's output finds that one or more steps taken by an operator were not properly performed, he or she can direct a rerun to thereby make sure that the patient gets a correct result.

Strawder's invention allows managers to monitor their operators and see which are having problems performing their duties.

Strawder's invention allows managers to monitor all exams performed and shows them the particular examination an operator is had problems with.

Strawder's invention allows managers to pinpoint in on the exact steps of an examination that an operator is having problems with so that they can target these steps for retraining.

Strawder's inventions also monitors all re-training efforts of managers to see if more training is necessary.

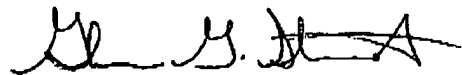
performing their duties.

My invention allows supervisors to know which particular examination an operator has problems with and to pinpoint the exact step or steps of that examination that the operator is having problems with so that they can target the step or steps for retraining.

My invention monitors all re-training efforts of management to see if more training is necessary.

My invention goes even further and is the easiest and most accurate way for a Radiology Clinical Instructor to monitor the skill & performance levels of a Student Radiologic Technologist. My invention will monitor each student's performance during each examination giving the Clinical Instructors the data that shows which of the students exceed, meet or falls short of their standard when they perform an exam. This system not only shows the Clinical Instructors each student's strength and weaknesses during an exam but also monitors the success of any re-training by the Clinical Instructors to strengthen or eliminate a weakness in the student's performance.

I, Glenn G. Strawder make this declaration under the penalties of perjury.



Glenn G. Strawder